REMARKS

Claims 1, 12, 13, 15-20, 24, 26-32, 34, 36-44, 47, 53, 67 and 73-80 are pending in the present application. Claims 1, 12, 13, 15-20, 24, 26-32, 34, 36-44, 47, 53, 67 and 75-80 stand rejected. Applicant's acknowledge the Office's recognition of the typographical error in the amendment filed 7 May 2009 regarding claim 67 and thank the Office for consideration of this pending claim. Further, Applicant's acknowledge the withdrawal of the previous rejection of claims 1-4, 6-24 and 26-56 under 35 U.S.C. 112, second paragraph.

Reconsideration of the application is respectfully requested.

I. Claims 1, 12, 13, 15, 17-18, 20, 24, 26-32, 34, 47, 53, 67 and 73-80 are Non-Obvious over DeLaHuerga, alone or in combination.

Claims 1, 12, 13, 15, 17-18, 24, 26-32, 34, 47, 53, 67 and 73-80 currently stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,408,330 to DeLaHuerga (hereinafter, "DeLaHuerga") in view of U.S. Patent No. 6,190,326 to McKinnon et al. (hereinafter, "McKinnon"). Claims 35-46 are rejected under 35 U.S.C. § 103(a) as being unpatentable over DeLaHuerga in view of McKinnon and further in view of US Patent No. 5363842 to Mishelvich as applied to claim 1 above and further in view of Admitted Prior Art. Claims 16 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over DeLaHuerga in view of McKinnon as applied to claim 1 and further in view of U.S. Patent No. 6,083,248 to Thompson (hereinafter, "Thompson"). These rejections are respectfully traversed, and withdrawal of the rejection is requested.

In the Office Action, the Office considers claim 1 to define an invention which is obvious over DeLaHuerga in view of McKinnon and further in view of Mishelvich. As the Office correctly notes, neither DeLaHuerga nor McKinnon disclose a medicament delivery system that is arranged to provide respirable delivery of a dose of medicament to a patient, which dose may be varied. However, Applicant's assert that it is not correct to find this feature disclosed in Mishelvich.

Mishelvich concerns an intelligent inhaler providing feedback to both a patient and a medical professional (e.g. see the title). As outlined in the 'Background of the Invention' (col. 1, line 6 et seq.), the amount of aerosol medication dispensed by an inhaler which is deposited at the therapeutically effective area of the lungs is dependent on the patient's inhalation airflow during release of the medication by the inhaler. To account for this, Mishelvich provides an inhaler which, during the medication delivery, detects how much air is inhaled by the patient through the inhaler with what time course and compares the time course either to a standard target envelope for that medication or to a patient specific target envelope programmed into the inhaler by a medical professional (col. 4, ll. 35-45). The comparison is used by the medical professional to evaluate the patient's performance to the target envelope. Moreover, the comparison is used to train the patient to create the correct inhalation profile, e.g. by feedback and real-time coaching to the patient (e.g. col. 2, ll. 52-57). The desired result of this is to foster the delivery of a uniform dose to the target sites of the patient's lung upon each inhaler usage so that a physician then knows any change in that patient's condition is not due to variation in the dose delivered to the target sites (col. 2, ll. 58-65).

In the Office Action, the Office relies on the teaching of Mishelvich referred to in the preceding sentence hereof as the motivation to combine Mishelvich with DeLaHuerga and McKinnon to provide a system which can deliver different doses of medicament. However, this passage in Mishelvich *teaches away* from varying the dose delivered by the inhaler. This passage refers to delivering a fixed amount of medication from the inhaler, and training the patient to inhale in a manner that result in the amount of that fixed dose reaching the target sites in the lungs being consistent from use-to-use. Changing the amount of medication delivered by the inhaler would result in a change in the amount of medication reaching the target lung sites, thereby undermining an objective of Mishelvich for a physician to know any change in the patient's condition is not related to dose variation at the target lung site.

Applicant's notes that Mishelvich does specify at column 6, lines 42-45 that "[t]he present device is also capable of being reprogrammed by the remote workstation to alter the dosage…..", and similar at column 11, lines 34-41 and at e.g. claim 9.

With regard to the passage at column 6, this is at the end of a paragraph which states that an important feature is the ability to insert standard metered-dose inhaler (MDI) canisters. The skilled person knows that a standard MDI canister is designed to deliver a fixed dose upon each inhaler usage. It is therefore considered that "alter the dosage" refers to changing the target envelope for the patient to change the amount of the fixed dose delivered by the MDI canister which hits the target lung sites.

It is considered such a reading also applies to the passage at column 11, which itself forms part of a paragraph concerning providing a target envelope for the patient to give a desired amount of medication to target sites of the respiratory tract.

Furthermore, claim 9 specifies that the "signalling means" of claim 2 is reprogrammable to vary the dose inhaled by the patient. According to claim 2, the "signalling means" has the function of providing feedback to the patient for improving patient inhalation. So, again, it is considered the "vary" feature relates to the amount of medicament deposited at the target lung sites which variation is to be achieved by having the "signalling means" coach the patient into producing a different type of inhalation profile.

Clearly, the term "dose" means different things in the present claims and Mishelvich. In the present claims, "dose" means the amount of medicament released by the system on actuation (which is a fixed amount in Mishelvich), whilst in Mishelvich "dose" means the fraction of the (fixed) released amount which deposits at the target lung site.

So, in conclusion, Mishelvich is not considered to disclose the feature in claim 1 of a medicament delivery system that is arranged to vary the dose of medicament deliverable to a patient. As a consequence, even if, simply for argument's sake, the combination of DeLaHuerga, McKinnon and Mishelvich was contemplated by the

person of ordinary skill in the art at the relevant date, this would still not result in the system of claim 1. Thus, claim 1 and its dependents are not prejudiced by the asserted references for at least this reason. The same considerations apply equally to claims 47 and 67 and their respective dependents.

As claims 16 and 19 depend on claim 1, and the aforementioned shortfall in disclosure in Mishelvich is not alleviated by Thompson, these claims are, for at least this reason, not obvious over the asserted combination of DeLaHuerga, McKinnon , Mishelvich and Thompson. The Applicant reserves the right to proffer additional arguments in defense of these claims if the need arises.

This submission is not intended to be, nor to be taken as, acquiescence or agreement by the Applicant with any of the other remarks made by the Office regarding the present claims and the content in the cited references.

Therefore, for at least the reasons stated above, applicants respectfully submit that claims 11, 12, 13, 15-20, 24, 26-32, 34, 36-44, 47, 53, 67 and 75-80 are not rendered obvious by the cited references or official notice taken by the Examiner. Thus, applicants respectfully submit that the rejections of claims 1, 12, 13, 15-20, 24, 26-32, 34, 36-44, 47, 53, 67 and 75-80 under 35 U.S.C. § 103(a) should be withdrawn and the claims allowed at this time.

Conclusion

All claim rejections being addressed in full, Applicant respectfully requests the withdrawal of the outstanding objections and rejections and the issuance of a Notice of Allowance.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR §1.16 or §1.17, and any necessary extension of time fees, to Deposit Account No. 07-1392.

Should the Examiner have any questions regarding the foregoing, Applicant respectfully requests that the Examiner contact the undersigned, who can be reached at (919) 483-9995.

Respectfully submitted,

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